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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/007,140

11/05/2001

Lyn Hughes

A01317

1934

21898 7590 01/03/2007
ROHM AND HAAS COMPANY
PATENT DEPARTMENT
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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/007,140

Applicant(s)

HUGHES, LYN

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2006 has been entered.
2. Claims 19-25 are objected to because of the following informalities: In claim 19, part d) "the" should be inserted before "filtration" for proper antecedence. In claim 19, part f, "from" should be deleted before "in the flow cell". In claim 19, the last line is redundant with part B). Appropriate correction is required.
3. Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, it is unclear what metes and bounds are intended by "performing an in vitro buccal dissolution test by" in part f. How does giving the test a different name make the test itself different? The examiner notes that applicant has disclosed that buccal dissolution differs from GI dissolution by having incomplete dissolution, shorter testing times and removing undissolved solids (Background of Invention), but it is not clear which of these is being claimed in that only removing undissolved small particles (indicating incomplete dissolution) is in the claim.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al in view of Olson (3,620,675).

Compton teaches a method for sampling a dissolution vessel having a stirrer and temperature control (col. 2, lines 41-48). A sample is withdrawn via needle 20 and particles are removed from the vessel and trapped in filter 32. Particle-free sample passes through the filter and may be passed to a flow-through analyzer, such as a flow injection analyzer or chromatographic system (col. 4, line 6-12).

Compton fails to explicitly teach passing release medium through the cell or adding a test sample or a UV flow cell.

Olson teaches a dissolution test with a UV flow cell analyzer 23.

It would have been obvious to provide a UV flow cell in the flow through analyzer of Compton in order to analyze dissolution samples as taught by Olson. It would have been obvious to provide release medium and sample in the dissolution vessel in order

to test the sample for dissolution as disclosed. Note that the medium “passes through” because it is supplied and withdrawn. With respect to claim 25, it would have been obvious to optimize the size of the needle to remove desired volumes at desired rates. Note further that the instant claims do not preclude back-flushing the particles into the dissolution cell or otherwise distinguish over Compton. In that Compton teaches in vitro dissolution testing in simulated biological fluids (col. 1, lines 16-18) with a rapid sampling rate (col. 2, line 3) and removal of solids by filtration, it is the examiner’s position that Compton teaches “buccal” dissolution, to the extent the term is definite.

4. Applicant’s arguments filed October 16, 2006 have been fully considered but they are not persuasive.

Note that “small particle” has been defined in the specification as pointed out by Applicant in the response filed March 17, 2006.

Applicant argues that neither Compton nor Olson teaches or discloses a “buccal” dissolution test, but it is unclear how giving the test a different name causes the method itself to define over the prior art. The combination of references teaches all the claimed method steps and therefore teaches the method, regardless of the name given it.

Applicant argues that one difference defining a buccal test over other dissolution tests is the sensitivity of the buccal cavity, but this is an in vitro test and it is unclear how mouth sensitivity translates into a difference in the in vitro test.

Applicant argues that Olsen teaches measurement over time, not in moments, but there is no claim limitation to the time of the instant test. Further, Olsen is relied

upon for the teaching of the flow cell UV analyzer, whereas Compton teaches the instant method using a different flow through analyzer.

Applicant argues that Compton teaches a sampling apparatus that withdraws samples and passes them through a filter, but fails to point to any method steps instantly claimed and not taught by Compton in view of Olson. Applicant argues that there is no motivation to combine Compton and Olson, but Compton teaches a dissolution testing method using a flow through analyzer, and Compton is relied upon to teach a specific flow through analyzer used for dissolution testing.

The examiner notes that there are clear differences between the instant method **as disclosed** and that of Compton, but the instant claims do not clearly and distinctly present those differences. For example, clearer claiming of (continuous?) flow streams, the dip leg for removing particles, the filter located distal from the dip leg, etc. might serve to define over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml